

Elementary Implantable Force Sensor

For Smart Orthopaedic Implants

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Abstract

Implementing implantable sensors which are robust enough to maintain long term functionality inside the body remains a significant challenge. The ideal implantable sensing system is one which is simple and robust; free from batteries, telemetry, and complex electronics. We have developed an elementary implantable sensor for orthopaedic smart implants. The sensor requires no telemetry and no batteries to communicate wirelessly. It has no on-board signal conditioning electronics. The sensor itself has no electrical connections and thus does not require a hermetic package. The sensor is an elementary L-C resonator which can function as a simple force transducer by using a solid dielectric material of known stiffness between two parallel Archimedean coils. The operating characteristics of the sensors are predicted using a simplified, lumped circuit model. We have demonstrated sensor functionality both in air and in saline. Our preliminary data indicate that the sensor can be reasonably well modeled as a lumped circuit to predict its response to loading.

Keywords

Implantable Sensor; Passive Resonator; Force; Pressure; Orthopaedic Surgery

Introduction

Implementing implantable sensors which are robust enough to maintain long term functionality inside the body remains a significant challenge. Sensors for orthopaedic applications are subjected to additional rigors because of the mechanical demands imposed on orthopaedic implants and tissues. Yet, orthopaedic “smart” implants have significant diagnostic value. Smart orthopaedic implants can be used to detect tissue healing, to monitor implant wear and loosening, and to determine optimal implant sizing (Ledet et al). These applications are realized by measuring physical parameters from inside the body such as force, pressure, temperature, displacement, or strain. Robust implantable sensors are a necessary element to enable smart implants.

Custom sensing systems have been used for fundamental research for decades (Ledet et al; Burny et al). However, systems with complex telemetry, batteries, and electrical interconnections are prone to early failure (Bassey et al; Davy et al; English et al; Ledet et al; Schneider et al). Furthermore, when complex sensing systems have been integrated into implants, substantial modification has been required of the implant itself (Bergmann et al; Brown et al; Damm et al; D’Lima et al). For these reasons, smart implants have not been realized in clinical practice.

The ideal implantable sensing system for orthopaedic applications is one which is simple and robust; free from batteries, telemetry, and complex electronics. The sensors must be able to withstand millions of cycles of mechanical loading without failure and must function in the *in vivo* environment. Importantly, the sensors must require minimal (or no) modifications to the implants which carry them into the body. The economics of medicine also mandates that the sensors must not significantly increase costs (Ledet et al).

To address these requirements, we have developed an elementary implantable sensor for orthopaedic smart implants. The sensor requires no telemetry and no batteries to communicate wirelessly. It has no on-board signal conditioning electronics. The sensor itself has no electrical connections and thus does not require a hermetic package. Prototype force sensors cost less than \$1 to fabricate and they do not require modifications to the host implants in most applications.

Basis of Resonator Design

The basic configuration of our sensors is essentially a simple parallel plate capacitor which is comprised of relatively fine wire formed into two Archimedean spirals on either side of a solid compressible dielectric disk, as shown in Figure 1. The two flat coils act as a parallel plate capacitor for which capacitance is ideally

given by:

$$C = \frac{\epsilon_r \epsilon_0 A_c}{l} \quad (1)$$

Where ϵ_r is the relative dielectric constant (relative permittivity), ϵ_0 is the vacuum permittivity (8.85419×10^{-12} F/m), A_c is the overlapping area of the conductors in each plate, and l is the distance between the plates. This expression is quite accurate (to within a few percent) if the plate dimensions are much greater than their separation.

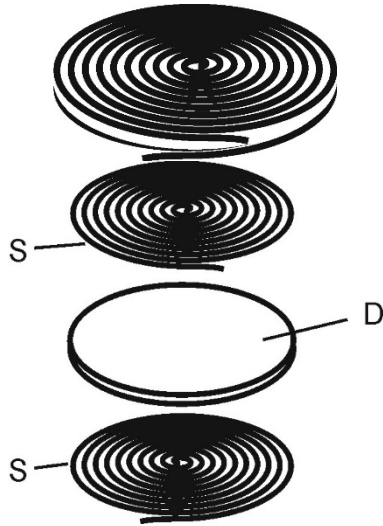


FIGURE 1 TWO ARCHIMEDEAN SPIRAL COILS (S) PLACED IN PARALLEL AND SEPARATED BY A DIELECTRIC (D) ACT AS AN L-C RESONATOR

An inductor is typically comprised of a coil which stores energy in its magnetic field. When an inductor is wired in series with a capacitor, it resonates at a characteristic frequency when exposed to oscillating electromagnetic waves. Through the inductor, charges flow back and forth between the plates of the capacitor. For a combination of a capacitor and an inductor, when each can be treated as a lumped circuit element, the resonant frequency is inversely proportional to the square root of the inductance and capacitance.

$$f_0 = \frac{1}{2\pi\sqrt{LC}} \quad (2)$$

When two flat Archimedean spiral coils (Figure 1) are placed in parallel with a thin dielectric layer between, the coils act as both the inductor and the capacitor plates (Collins). To model the characteristics of this resonator, a lumped circuit model can be used to elucidate the key design issues. This approach has been taken in the analysis of simple planar resonant coils for decades and now provides a useful tool in integrated circuit design. We have considered several of the available models both for convenience and to validate our results. The first lumped element model is widely applied and comes from Wheeler (Wheeler et al; Wheeler et al) and was expanded by Terman (Terman

et al):

$$L_{coil} = \frac{a^2 N^2}{(2a + 2.8b) \times 10^5} H \quad (3)$$

Here L is inductance, N is the number of turns in the coil, a is the mean radius of the coil and b is the depth of the coil ($r_{outer} - r_{inner}$) in meters as illustrated in Figure 2.

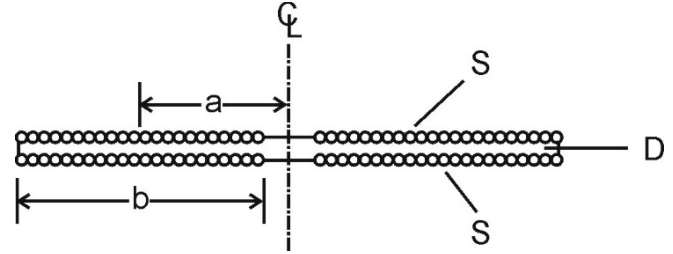


FIGURE 2 A CROSS-SECTION THROUGH TWO PARALLEL SPIRAL COILS (S) SHOWS THE DIELECTRIC LAYER (D) AND THE MEAN RADIUS (a) AND DEPTH (b) OF THE COILS

Using this approximation, errors are supposed to be less than 5% when $b > 0.2$. However, errors can be as large as 20%, compared to more contemporary models, especially as frequency is increased (Connor et al). Errors are generally even larger when two coils in close proximity are addressed. A geometry similar to the one shown in Figure 2 was studied by Collins (Collins et al) with the major difference that the coils were joined at the periphery by continuing the wire from one spiral to the other. The resonant frequency of the connected two-coil structure was found to be about half the frequency of the individual coils as predicted by Terman's versions of Wheeler's formulas. Collins' results demonstrate the limitations of the lumped circuit element approach.

A more recent expression, developed by Mohan (Mohan et al) for modeling on-chip inductors for integrated circuit design, is a more accurate estimation of inductance:

$$L_{coil} = \frac{\mu_0 N^2 d_{avg} c_1}{2} \left(\ln \left(\frac{c_2}{\rho} \right) + c_3 \rho + c_4 \rho^2 \right) \quad (4)$$

where μ_0 is the permeability of free space $= 4\pi \times 10^{-7}$, d_{avg} is the average diameter $= \frac{1}{2}(d_{out} + d_{in})$, ρ is the fill ratio $= (d_{out} - d_{in}) / (d_{out} + d_{in})$, and c_1 through c_4 are constants based on the geometry of the coil. For a circular Archimedean coil, $c_1=1$, $c_2=2.46$, $c_3=0$, and $c_4=0.2$. Like Wheeler's lumped element model, this expression is less accurate for two nearby coils, but is useful to provide a reasonable estimate of system parameters.

For two parallel coils, modeled with lumped circuit elements, the total inductance is then

$$L_{Total} = L_{coil 1} + L_{coil 2} + 2M \quad (5)$$

where M is the mutual inductance and is related to the two coil inductances by

$$M = k\sqrt{L_{coil1}L_{coil2}} \quad (6)$$

where k is the coupling coefficient.

From Equations 1-6, the resting resonant frequency can be calculated for the parallel coil L-C circuit based on geometric and material properties. The parallel coils function as an elementary L-C circuit whether the coils are connected electrically or not. Relative to disconnected coils, shorting one set of ends together effectively combines the two inductors into one, which doubles the number of turns (or makes the coupling of the coils nearly perfect). This will approximately double the inductance relative to disconnected coils. In addition, there are also wave effects which affect the inductance. The net effect of disconnecting the coils is that the mutual inductance is approximately halved (or smaller) relative to connected coils.

Basis of Force Sensor Design

The elementary LC resonator described above can function as a simple force transducer by using a solid dielectric material of known stiffness between the two coils. From Equation 1, capacitance varies as a function of coil spacing. Application of an axial load which results in deformation of the dielectric will change coil spacing. This in turn modulates capacitance and frequency as in Equation 2. Alternatively, the sensor can measure shear forces if configured so that application of shear changes the overlapping area (A) of the capacitor as in Equation 2.

In the axial application, an axial load results in compression of the dielectric. This causes a decrease in plate spacing which in turn increases capacitance and decreases the resonant frequency. The change in frequency is governed by Equations 7-14.

$$\text{Relating strain to deformation} \quad \varepsilon = \frac{\Delta l}{l} \quad (7)$$

$$\text{and stress to force} \quad \sigma = \frac{F}{A_T} \quad (8)$$

$$\text{For a linearly elastic material,} \quad E = \frac{\sigma}{\varepsilon} \quad (9)$$

$$\text{and } \Delta l = \frac{\Delta F l}{AE} \quad (10)$$

Combining Equations 1 and 10

$$\Delta C = \frac{\epsilon A}{\Delta l} \text{ and } C_f = C + \Delta C \quad (11)$$

Where C is the unloaded capacitance, C_f is the capacitance under load, E is the modulus of elasticity for linearly elastic materials, σ is the stress, ε is the strain, l is the original spacing between coils, Δl is the change in coil spacing, F is applied force (compression is negative), A_T is the total overlapping area, and $\square = \square_r \square_0$ is the permittivity.

Ultimately the relation of interest is how axial force

modulates the resonant frequency. Combining Equations 2 and 10 yields

$$\Delta f = \frac{1}{2\pi \sqrt{\frac{L\epsilon A C}{\Delta F l}}} \quad (12)$$

Defining

$$B = \frac{1}{2\pi \sqrt{\frac{L\epsilon E A_C A_T}{l}}} \quad (13)$$

Then

$$\Delta f = B(\Delta F)^{1/2} \quad (14)$$

Based on this relationship, if the geometric and material properties defined in Equation 13 are constant, then Equation 14 can be used to predict the change in sensor frequency in response to an applied axial force. To validate this relationship, we have fabricated prototype coil sensors for testing and evaluation.

Sensor Fabrication

Prototype sensors were fabricated from 34, 38, or 40 gauge copper magnet wire and manually wound around a mandrel. During winding, the wire was wrapped through pre-cured epoxy (M-Bond AE-15, Vishay Measurements Group, Raleigh, NC) which was used to maintain the shape of the coil once cured. Thin layers of polydimethylsiloxane (PDMS) resin were cut using a microtome cryostat (Microm International GmbH, Waldoff, Germany) to function as the solid dielectric for the sensors.

Sensors were fabricated using various combinations of physical parameters including wire gauge, coil diameter, dielectric thickness, etc. Sample physical properties are shown in Table 1 and a prototype sensor is shown in Figure 3.

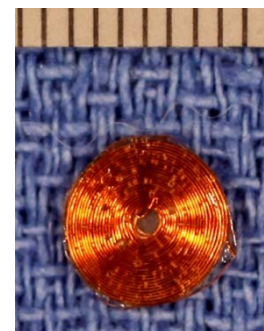


FIGURE 3 SENSORS ARE COMPRISED OF TWO FLAT PARALLEL SPIRALS WITH A DIELECTRIC BETWEEN. PROTOTYPE SENSORS WERE FABRICATED FROM COPPER WIRE. THE SCALE SHOWN IS MILLIMETERS

Sensor Testing

Manually fabricated sensors were tested and sensor resonant frequency was read with a 75 ohm Agilent E 5062A L-RF Network Analyzer (Agilent, Santa Clara,

CA) with a 75 ohm co-axial cable and a handmade prototype loop antenna. The sensors were read using the “grid dip” method (Dezettel). In this method, the external antenna powers the resonant sensor circuit through inductive coupling. The resonant frequency is detected by a dip in the output energy which changes in the vicinity of a resonant circuit that is tuned to the frequency of the oscillator.

Sensors were fabricated and tested to validate the lumped element model. Using a network analyzer, the resonant frequency of unloaded sensors was measured in air and in saline (0.9% NaCl). Sensors were then mechanically tested in air and saline to measure force sensitivity and the force-frequency relationship. Sensors were loaded in axial compression incrementally in steps of 10 N up to 100 N for five repeated cycles at a rate of 1 mm/minute using a mechanical testing machine (MTS Systems Corp., Cary, NC). Applied force and sensor resonant frequency data were simultaneously collected at every force increment. From these data, the resting frequency and force sensitivity to axial load were measured.

Sensor Validation

The operating characteristics of the sensors are predicted using a simplified, lumped circuit model as

described above. This is based on the inductance and resistance of each coil and the parallel plate capacitance linking the two coils. When tested in air, sensors performed well relative to analytical predictions. Resting (unloaded) frequencies ranged from approximately 30-100 MHz as shown in Table 1. This was consistent with theoretical resonance of sensors using the idealized model as in Equations 2 and 13.

However, the values of the resonant frequencies determined using this simple approach are not particularly accurate in all cases. Consider sensors 5, 6, and 7 in Table 1, which are chosen for analysis because they were constructed with the largest dielectric thickness. These three sensors have nearly identical coils (they were, in fact, built to be the same) and only slightly different dielectric dimensions. Based on the lumped element models presented, sensor 7 should have the lowest operating frequency and sensor 6 the highest, based on the gap between the two coils. However, this is not the case.

All of the coils in Table 1 were manually fabricated and thus have inherent irregularities. The basic lumped element models are not robust enough to account for these irregularities, but the sensors with the thicker dielectric will generally be less sensitive to these variations.

TABLE 1 SENSORS OF VARIOUS DESIGNS WERE FABRICATED AND TESTED

Sensor #	1	2	3	4	5	6	7	8	9	10
Conductor Diameter (mm)	0.101	0.101	0.080	0.080	0.101	0.101	0.101	0.101	0.101	0.101
Coil Diameter (mm)	6.8	6.8	7.5	5.3	6.5	6.5	6.5	6.5	6.5	6.5
Number of Turns	24.75	24	36.75	25	22.5	22.5	22.5	22.5	22.5	22.5
Interwire Spacing (mm)	0.011	0.014	0.005	0.001	0.015	0.015	0.015	0.015	0.015	0.015
Gap Between Coils (μm)	48.26	31.75	26.67	44.56	315.56	292.7	371.44	70.45	50.13	62.83
Measured Resonance (MHz)	61.12	55.45	31.28	101.93	99.63	93.99	94.53	96.46	112.93	87.88

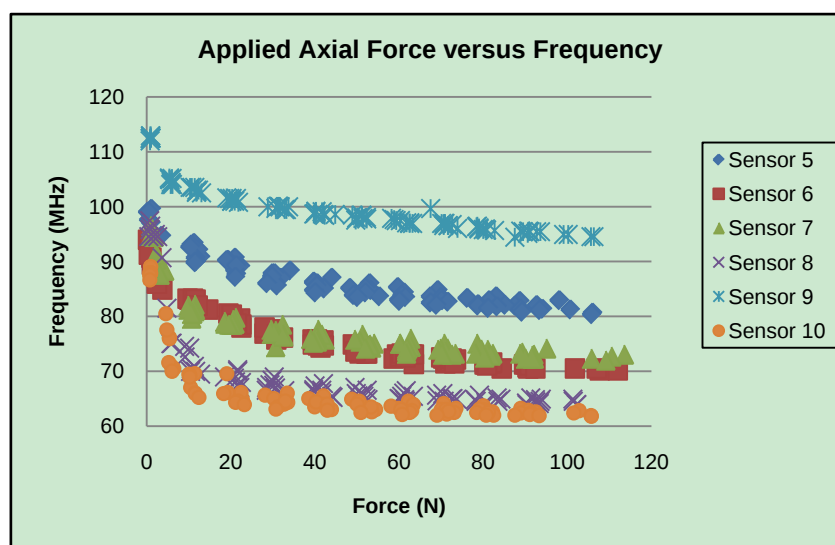


FIGURE 4 AS PREDICTED BY THE ANALYTICAL MODEL, THE RESONANT FREQUENCY OF THE SENSORS DROPS WITH APPLIED AXIAL COMPRESSIVE LOADING. DATA FROM SIX SENSORS ARE SHOWN

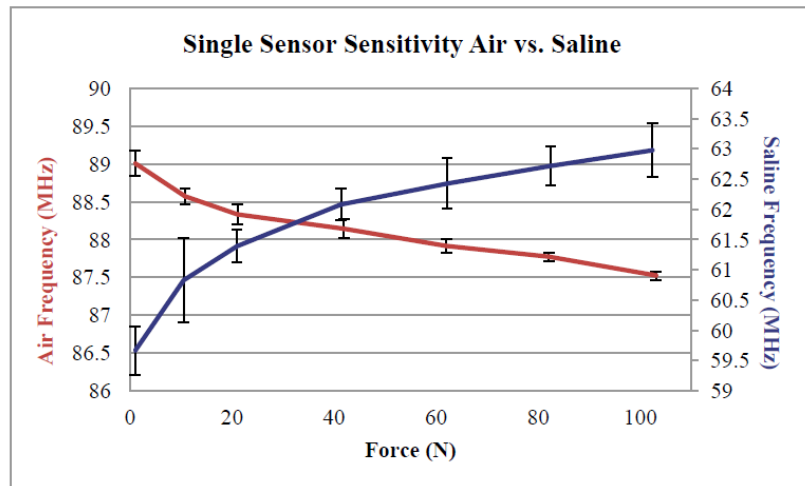


FIGURE 5 PERFORMANCE OF THE SENSORS AT RESTING FREQUENCY AND IN RESPONSE TO LOAD DIFFERED IN SALINE RELATIVE TO AIR

For a “typical” sensor, coil diameter = 6.5 mm, diameter of hole in center of coil = 1.3 mm, gap between coils = 0.3 mm, number of turns = 22.5, wire diameter = 0.101 mm, inter-wire spacing (gap between windings) = 0.015 mm and approximate value for the insulator dielectric of 3, the two lumped element formulas for coil inductance yield: $L_{coil1} = L_{coil2} = 1.73 \mu\text{H}$. Assuming a relatively small coupling coefficient $k = 0.2$, the total inductance is $L \approx 4.15 \mu\text{H}$. The capacitance, assuming 6.5 mm diameter coils with a 1.3 mm diameter hole in the center is $C \approx 2.47 \text{ pF}$. Doubling the calculated resonant frequency for unconnected coils is then $f = 98.8 \text{ MHz}$ which compares favorably with the mean of sensors 5, 6, and 7 (97.6 MHz).

Effect of Media

While the simple analytical model predicts the performance of the sensors in air, testing in saline produced unexpected results. When tested in saline, the resting resonant frequency and response to load changed substantially relative to testing in air. As shown in Figure 5, the resting frequency decreased in saline relative to air, but increasing axial load caused a rise in sensor frequency.

Based on the simple lumped circuit model, as the two coils in the resonator are compressed together, the capacitance should increase, which should decrease the resonant frequency. This indeed does happen in air, but not in saline. The performance in saline can be explained using the simple model with additional considerations for multiple dielectric materials.

Ideally, the insulating region between the two Archimedes spiral coils should be uniformly filled with a single, well-behaved dielectric. However, in our prototypes, there are generally at least three dielectric

regions. They include: PDMS which is the main dielectric chosen for its biocompatibility and mechanical characteristics. Epoxy which is used to hold the spiral coils together once they are wound. Air or saline which is found between the coils and the dielectric materials because the manually fabricated sensors are not precisely planar and contain small gaps in several locations in the sensor.

Since the dimensions of the sensors are all small compared to the wavelengths of the RF fields used to sense their resonant frequency, it is possible to take the various dielectric materials into account by using the volume average of each dielectric constant (Brown and Fuller). That is, the average dielectric constant of a medium will be

$$\epsilon_{eff} = \frac{\epsilon_1 V_1 + \epsilon_2 V_2 + \epsilon_3 V_3}{V} \quad (14)$$

where V is the total volume and V_i is the volume of constituent i . This is a low frequency model that works as long as the sensor is small (Cumming).

Using the data in Figure 5, there are two distinctive features of the curves. First, the resting frequency in saline is significantly lower than in air and, second, the frequency falls with load in air and rises in saline. Qualitatively, these two features occur because part of the dielectric region is filled with air when the sensor is tested in air and part is filled with saline when the sensor is tested in saline. This simple difference dictates the response of the sensor to load in the respective media.

Since the salt content of 0.9% saline is small, the following discussion is based solely on its dielectric constant which is approximately 80, and not on its conductivity. An additional assumption is that the air or saline regions are relatively small compared to the overall volume of dielectric. This is confirmed based

on visual examination of the sensor.

For the typical sensor described above (6.5 mm diameter, 22.5 turns, etc.), using a dielectric constant of PDMS and epoxy of approximately 3, and based on Equations 4 and 5, the inductance of one coil is approximately 1.73 μH and based on Equation 1, the capacitance with no air or water is about 2.47 pF. (These values are chosen to be typical.) The resting resonant frequency is given by Equation 2. Assuming that inductance is not affected by the saline (because it has a small conductivity, less than 1 S/m), then the dependence of frequency of the unloaded sensor in various media depends solely on the effective dielectric constant.

$$f = \frac{1}{2\pi \sqrt{L \left(\frac{\epsilon_{\text{eff}} A C}{l} \right)}} \quad (15)$$

The total spacing between the coils equals the sum of the constituents (air or saline + dielectric) which is 0.3 mm. Thus, $p + q = l = 0.3$ mm where p is the thickness of the air or saline and q is the thickness of the dielectric. Then from Equation 14, the effective dielectric constant is:

$$\epsilon_{\text{eff}} = \frac{p\epsilon_1 + q\epsilon_2}{l} \quad (16)$$

where the dielectric constant of air or saline is ϵ_1 and the dielectric constant of PDMS is ϵ_2 . From the data shown in Figure 5, the resting resonant frequency in air is 89.0 MHz and in saline is 59.5 MHz. Substituting these values and the dielectric constants for saline and air into Equations 15 and 16, the square of the ratio of the frequencies is:

$$\left(\frac{89.0}{59.5} \right)^2 \approx 2 = \frac{80p + 3q}{p + 3q} = \frac{80p + 3(0.3 - p)}{1 + 3(0.3 - p)}$$

Solving for p indicates that a gap as small 0.01 mm in a 0.30 mm dielectric can account for the change in resting frequency in air versus saline. Thus, even a very small volume fraction of air or saline (3%) can account for the resting frequency difference shown in Figure 5.

From the data in Figure 5, under load in air, the frequency drops by 1.5 MHz or 1.6% when compressed with 100 N. Under load in saline, it rises by 3.3 MHz or 5.5%. As the sensor is being loaded, two parameters are changing which modulate the capacitance: (1) The spacing between the two coils is being reduced. (2) The dielectric constant is changing as the air or saline is being squeezed out. Because both of these phenomena occur simultaneously, it is difficult to decouple the effects in our prototypes. Future work will target a more robust characterization

of these effects.

Substituting Equation 16 into 15 and assuming a single dielectric with no air or saline gap ($\epsilon_{\text{eff}} = 3$ and $l = q$), loading a sensor to 100 N results in a frequency shift (decrease) to a little less than 87.5 MHz. Thus, the combination of removing the air and some deformation of the solid dielectric can easily account for the change in frequency. Both changes reduce the frequency, so it is not possible to determine how much of each effect is occurring, especially because of the irregular nature of the surfaces in the manually fabricated sensors.

Discussion

We have demonstrated the functionality of an elementary wireless force sensor to measure axial loads. The sensor is simple and has no electrical connections. It is a three component passive LC resonator, the frequency of which is sensitive to axial mechanical loads. We have demonstrated sensor functionality both in air and in saline. Our preliminary data indicate that the sensor can be reasonably well modeled as a lumped circuit to predict its response to loading. However, the lumped circuit model has limitations.

There are many papers available that attempt to provide simplified lumped element models of spiral coils, with Mohan's work being among the most popular. While these models do indeed provide a useful tool for designing inductors, more elaborate models are required to obtain highly accurate results. Ellstein (Ellstein et al) modeled double spiral inductors like the ones used here as connected circular loops. Each loop was characterized by an inductance and resistance and a capacitance at each end for a total of 4 lumped elements per loop. One to 12 loops per coil were addressed and excellent agreement (with a few percent error or less) was obtained with both measured frequencies and frequencies predicted by commercial numerical analysis tools. Particularly good agreement was found when a via was added between the two coils to address Collins' configuration. The halving of the resonant frequency was observed, as reported by Collins. In addition, a standing current wave was also observed with a peak at the via and minima at the open ends of the coils, demonstrating that wave phenomena were present. The simple lumped circuit models used above do not consider wave phenomena and, thus, cannot be expected to be highly accurate. Note that for the sensors with thinner

dielectrics, wave phenomena will be more pronounced which will add to errors in predictions based on the simple models. However, another observation does justify the use of these models. The key to the operation of the sensors is the change in capacitance with compression. All of the many capacitances used by Ellstein to model the double spirals show the same changes with compression as seen with the single capacitor model.

Much of the inability of the simplest lumped circuit models to predict the frequency of the sensors with thinner dielectrics can also be explained by including some air in the dielectric region. Thinner dielectrics will have relatively more construction issues just because of their size. If the effective dielectric constant is roughly the average of air and the insulator, then the capacitance will be reduced significantly and the predicted frequency increased, bringing it closer to the measured frequency.

Future Work

To further validate the sensor for *in vivo* applications, second generation implantable sensors will be fabricated from biocompatible materials. The spiral conductors and dielectric are the only two constituents of the sensor. The fundamental relationships governing the function of the sensor are not material dependent, but the specific performance (range, sensitivity, etc.) of the sensor are largely dictated by the dielectric. Both its material properties and its electrical properties will dictate the resting frequency as well as its sensitivity to load. Moisture absorption of the dielectric at 37° C will also contribute to the properties of the sensor *in vivo* including drift and sensitivity to load.

While the sensors as a whole require no hermetic encapsulation because there are no electrical connections, the windings of the coils must be insulated from each other and from the other coil. Additionally, as our prototype data demonstrate, gaps in the dielectric can alter the properties of the sensor. For clinical use, each individual conductor coil will be hermetically sealed to make the sensors immune to changes in dielectric properties from the aqueous environment. For batch production, microfabrication techniques will be used to deposit layers of conductor and dielectric with no gaps. These much more precise manufacturing processes will make it possible to more precisely determine where the conductors and insulators are located which will justify the use of numerical methods to more fully and accurately

characterize the operation of the sensors.

In order to function as an effective implantable sensor, it will have to be robust enough to withstand the demands of the *in vivo* environment. Sensors may be exposed to sustained static loads, thus minimal creep is essential. Sensors may be exposed to cyclic dynamic loading, thus minimal hysteresis is also critical. A highly hydrophobic biocompatible polymer with high stiffness will likely afford the most optimal properties for a robust implantable sensor for orthopaedic applications. Because the sensors are sensitive to both axial and shear forces, when used clinically, they will need to be integrated into implants in ways that either expose them to axial loading and prevents shear, or exposes them to shear and prevents axial load. The combination of shear *and* axial loading potentially confounds the sensitivity of the system. Sensors will also need to be integrated in metal implant systems in ways which the conductor coils are insulated from the metal of the implant.

Conclusions

The sensors described here are exceptional in that they are extremely simple in principle. There are no electrical connections and therefore there are no electrical connections which can fail. There are only three components to each sensor (two coils and a dielectric), and thus the sensors are simple to fabricate and easy to tune for optimizing the design. The elementary design results in an extremely inexpensive sensor, less than \$1 in cost for prototypes and expected less than \$10 in cost for implantables. Batch fabrication techniques will likely reduce the cost further. Due to their small size, integration into host implants will likely involve little to no modification of the implant itself. Because of the elementary design of the sensors, it is expected that they will gain acceptance for use in clinical practice. We have validated the function of an elementary passive resonator as a force sensor. Future work will be aimed at optimizing sensor properties and the external electronics in preparation for applications in orthopaedic surgery.

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